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Sonoma Orthopedic Products, Inc.
650 Larkfield Center, Suite C
Santa Rosa, CA 95403
Ph: 707-526-1335
Fax: 707-540-6001

AUG 2 8 2009

510(k) Summary

Submitter's name	Sonoma Orthopedic Products, Inc.
Address	650 Larkfield Center, Suite C Santa Rosa, CA 95403
Phone Number	707-526-1335 ext. 255
Fax Number	707-540-6001
Name of contact person	Carlos Gonzalez
Date summary was prepared	January 14, 2008
Proprietary name/Trade name	WavEon™ WRx
Common Name	Intramedullary Distal Radius Fixation Device
Classification Name	Plate, Fixation, Bone 21 CFR 888.3030, HRS
Predicate Device	Sonoma Orthopedic Products Inc. Ensplint Rx, K071809
Description of device	The WavEon™ WRx configuration consists of a flexible implant manufactured from stainless steel.

Intended use of device

The Waveon™ WRx (WristRocket™ Distal Radius System) is intended to be used for the fixation of unstable distal radius fractures in which closed reduction is not suitable:

- Joint destruction and/or subluxation visible on x-ray;
- Osteotomy and repair of distal radius malunion with or without bone graft;
- Non-displaced fractures.
- Transverse fractures of the distal radius with or without comminution (e.g. AO classifications A2 and A3);
- Transverse fractures of the distal radius with an extension into the joint with or without comminution (e.g. AO classification C2 and C1 respectively);
- Failed fracture fixation with or without bone graft for the types of fractures above;
- The above types of fractures (i.e. AO classifications non-displaced transverse, A2, A3, C1 and C2) in which reduction has been lost following fixation with percutaneous pins with or without an external fixator.

Comparison to Predicate Device

The WavEon™ WRx is the new trade name, for the Ensplint predicate device. This submission extends the indications for use to C2 Distal Radius Fractures (AO classification). Only minor differences are incorporated in this model that do

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	not affect safety or effectiveness. Extended indications is requested to include C2 Distal Radius fractures.
Performance Data (Non clinical)	Equivalent to the predicate, the WavEon™WRx device meets the requirements of ASTM 1264. Further, cadaver studies demonstrate that the implant can be safely inserted, reduce and fixate C2 fractures. Therefore, the WavEon™WRx is substantially equivalent to the predicate and Safe and Effective for the extended application.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

AUG 2 8 2009

Sonoma Orthopedic Products, Inc.
% Mr. Carlos Gonzalez
650 Larkfield Center, Suite C
Santa Rosa, CA 95403

Re: K090304
Trade/Device Name: WavEon WRx
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS, HSB
Dated: July 15, 2009
Received: July 21, 2009

Dear Mr. Gonzalez:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/cdrh/comp/ for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Buehler
for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K090304

Device Name: WavEon™ WRx

Indications for Use:

The Waveon™ WRx (WristRocket™ Distal Radius System) is intended to be used for the fixation of unstable distal radius fractures in which closed reduction is not suitable:

- Joint destruction and/or subluxation visible on x-ray;
- Osteotomy and repair of distal radius malunion with or without bone graft;
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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

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